Protecting Life Science

Isofield CR++

600mm (24”) Sterile latex Cleanroom gloves

Last updated **09 Jul 2025**

PRODUCT CODE

REF **10360**

SIZE 6.0	1036060	SIZE 8.0	1036080
SIZE 6.5	1036065	SIZE 8.5	1036085
SIZE 7.0	1036070	SIZE 9.0	1036090
SIZE 7.5	1036075		

CE 2797 UK CA 0086 AQL 0.65 STERILE R

PRODUCT INFO

Sterile latex Cleanroom gloves
600mm (24”) shoulder length
Hand-specific
Natural colour
Textured palm & fingers
Beaded cuff
Low endotoxin levels
Gamma irradiation, minimum 25kGy
Sterility Assurance Level 10^{-6}
Food Safe. Complies limits established under Regulation (EU) No 10/2011
Protein level less than 50µg/g
IPA resistant ink pouches

CLEANROOM COMPATIBILITY

GMP Grade A cleanroom
GMP Grade B cleanroom

ISO Class 4 cleanroom
ISO Class 5 cleanroom

Class 10 cleanroom
Class 100 cleanroom

QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5 cleanroom

Physical properties comply with European medical glove standard EN 455-2:2015

APPLICATIONS

Loading and unloading of lyophilizer or depyrogenation tunnel

Blending granulates and powders

Transfer of partially closed containers used in freeze-drying

Sterile lyophilization of parenteral drug products

STORAGE & SHELF LIFE

Store in a dry, cool place (< 40°C) away from direct sunlight

Do not expose open cartons to prolonged direct fluorescent light

Five (5) years from date of manufacture

PACKAGING

1 pair per inner PE wallet,

1 PE wallet per sealed PE pouch,

10 pouches per PE bag,

10 sealed PE bags per lined carton (100 pairs)

PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM*	MILS	TEST METHOD
Finger tip	0.20	7.87	EN 455-2:2015
Palm	0.18	7.09	EN 455-2:2015
Cuff	0.12	4.72	EN 455-2:2015

** +/- 0.02mm*

LENGTH	MIN	TYPICAL	TEST METHOD
From tip of middle finger to edge of cuff	590mm	600mm	EN ISO 21420:2020

STRENGTH PROPERTIES	FORCE AT BREAK	TEST METHOD
Throughout shelf life	≥ 9.0 N	EN 455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	0.65 - Level 3 of 3	EN 374-2:2016

CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm^2)	< 1200	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm^2)	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.121	IEST-RP-CC005.4
Nitrite (NO_2)	0.013	IEST-RP-CC005.4
Bromide (Br)	ND	IEST-RP-CC005.4
Nitrate (NO_3)	0.011	IEST-RP-CC005.4
Phosphate (PO_4)	ND	IEST-RP-CC005.4
Sulphate (SO_4)	0.013	IEST-RP-CC005.4
Lithium (Li)	ND	IEST-RP-CC005.4
Sodium (Na)	0.012	IEST-RP-CC005.4
Potassium (K)	0.031	IEST-RP-CC005.4
Calcium (Ca)	0.072	IEST-RP-CC005.4
Magnesium (Mg)	0.023	IEST-RP-CC005.4
Zinc (Zn)	ND	IEST-RP-CC005.4

** ND = Not Detected*

TECHNICAL PROPERTIES

NORM	TEST REFERENCE	EXPLANATION
Chemical innocuousness	EN ISO 21420:2020	Ensures the gloves do not adversely affect the health of the user. The materials present in the gloves must not release substances that are toxic
Sizing & dexterity	EN ISO 21420:2020 and EN ISO 374-2:2019	Determines sizing compliance and glove dexterity
Air leak & water leak	EN ISO 374-2:2019	Assesses the resistance of the glove to penetration
Chemical degradation	EN ISO 374-4:2019	Determines the resistance to degradation by dangerous chemicals
Chemical permeation	EN 16523-1:2015+A1:2018	Determines the resistance of protective glove materials to permeation by potentially hazardous non-gaseous chemicals
Viral Penetration	EN 16604:2004	Assesses the resistance of glove materials to penetration by blood-borne pathogens
Endotoxin test	EN 455-3, USP	Specifies requirements for the evaluation of biological safety for gloves
Sterility Validation Test	EN ISO 11137 Part 2:2015	Specifies requirements for the development, validation and routine control of a radiation sterilization process
EU Type Certificate	EN ISO 374-1:2016+A1:2018 Type B EN ISO 374-5:2016 EN ISO 374-4:2019	The applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product
UKCA Type Certificate	EN ISO 374-1:2016+A1:2018 Type B EN ISO 374-5:2016 EN ISO 374-4:2019	The applicable essential health and safety requirements of PPE Regulation (2016/425) as brought into UK law and amended as a Category III product

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	5.80 - 7.05kg	5.80 - 7.05kg
Carton size	W28 L32 H30cm	W28 L32 H30cm
Nett weight	3.60 - 4.85kg	3.60 - 4.85kg
Air freight pallet	Max height: 135cm Layers: 4 Cartons: 32	Max height: 135cm Layers: 4 Cartons: 48
Sea freight pallet	Max height: 165cm Layers: 5 Cartons: 40	Max height: 165cm Layers: 5 Cartons: 60

DOCUMENTATION

CERTIFICATE OF CONFORMANCE (COC)
CERTIFICATE OF ANALYSIS (COA)
CERTIFICATE OF IRRADIATION (COI)

View sample of COC, COA, COI

DECLARATION OF CONFORMITY (DOC)

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FACTORY RELATED CERTIFICATIONS

To request ISO9001 Certificate, please email us

Country of origin: **Malaysia**
HS Code: 4015199000

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